

## AMENDMENT AND RESPONSE TO OFFICE ACTION

Docket No. 15872.091

Title: "Bioactive Compounds Protection Method and Compositions Containing the Same"  
U.S. Serial No. 10/561,541AMENDMENTS TO THE CLAIMS

Please replace the claims with the following amendments:

1-87. (Cancelled).

88. (Withdrawn) A method for encapsulating or embedding a heat sensitive bioactive ingredient in mammalian newborn food formulation or mammalian newborn feed formulation, comprising the steps of;

- (i) mixing a heat sensitive bioactive ingredient with an encapsulating material, wherein said encapsulating material is food-grade, feed-grade materials, either alone or in combination, with a liquid, forming a liquid blend,
- (ii) drying the liquid blend forming a dry blend,
- (iii) coating the dry blend with at least one additional encapsulating layer;
- (iv) mixing the dry blend with at least one additional food-grade or feed-grade material; and
- (v) adding the dry blend to the mammalian newborn formulation, wherein the steps of admixing all of the ingredients and drying are conducted at a temperature below 50°C, such that the activity of the heat sensitive bioactive ingredient is substantially maintained, thereby encapsulating or embedding the heat sensitive bioactive ingredient in a mammalian newborn formulation.

89. (Withdrawn) The method of claim 88, wherein the mammalian newborn food or feed is a human infant formula.

90. (Withdrawn) The method of claim 88, wherein the mammalian newborn food or feed is a milk replacer, a milk substitute or a combination thereof.

91. (Withdrawn) The method of claim 88, wherein the step of drying the liquid blend further comprises a step of grinding the dry blend.

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92. (Withdrawn) The method of claim 88, wherein the heat sensitive bioactive ingredient is selected from the group consisting of insulin, a glycoprotein, an immunoglobulin, a peptide, a polypeptide, a hormone, an enzyme, IGF-I, IGF-II, EGF alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component or complexes of soluble CD4, tissue plasminogen activator, a pharmaceutically acceptable salt thereof, an analog thereof, a variant thereof or a combination thereof.

93. (Withdrawn) The method of claim 88 wherein the step of drying the liquid blend is performed by freeze drying, spray freezing, low temperature vacuum heat drying, low temperature spraying drying or a combination thereof.

94. (Withdrawn) The method of claim 93, wherein said freeze-drying is preceded by spray-freezing.

95. (Withdrawn) The method of claim 94, wherein the spray-freezing is preceded by extrusion.

96. (Withdrawn) The method of claim 93, wherein said freeze drying, spray freezing, extrusion or a combination thereof, results in glassy droplets, containing at least one bioactive compound and at least one food-grade or feed-grade encapsulating material, either alone or in a combination.

97. (Cancelled).

98. (Withdrawn) The method of claim 88, wherein the mammalian newborn food or feed is specifically formulated for the consumption of the genera of primate, bovine, ovine, canine, feline, and caprine.

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99. (Withdrawn) The method of claim 88, wherin the food-grade or feed-grade encapsulating material is polysaccharide, maltodextrin, milk powder, whey protein, lipid, gum Arabic microcrystalline cellulose or a combination thereof.

100. (Cancelled).

101. (Withdrawn) A newborn edible food or feed formulation comprising a heat sensitive bioactive ingredient, encapsulated by the method of claim 88.

102. (Cancelled).

103. (Withdrawn) The formulation of claim 101, wherein the formulation is in a form of a powder, a solution, a spread, an ointment, a semi-solid, a solid or a combination thereof.

104. (Withdrawn) The formulation of claim 101, wherein the bioactive ingredient being encapsulated or embedded is released upon contact with a liquid.

105. (Withdrawn) The formulation of claim 101, comprised of uniformly sized particles of encapsulated bioactive ingredient, wherein the particles have a radius between about 1  $\mu$ m and 5,000  $\mu$ m.

106. (Currently Amended) A method for improving the health status of a mammal comprising the step of administering to the mammal a newborn edible food or feed formulation comprising a heat sensitive bioactive ingredient according to claim 101 encapsulated by a method comprising the steps of:

- (i) mixing the heat sensitive bioactive ingredient with an encapsulating material, wherein said encapsulating material is food-grade or feed-grade materials, either alone or in combination, with a liquid, forming a liquid blend;
- (ii) drying the liquid blend forming a dry blend;
- (iii) coating the dry blend with at least one additional encapsulating layer;

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(iv) mixing the dry blend with at least one additional food-grade or feed-grade material; and

(v) adding the dry blend to the mammalian newborn formulation, wherein the steps of admixing all of the ingredients and drying are conducted at a temperature below 50°C, such that the activity of the heat sensitive bioactive ingredient is substantially maintained;

thereby improving the health status of a mammal.

107. (Currently Amended) The method of claim 108, wherein said health status is growth, development of the mammal, or a combination thereof.

108. (Withdrawn) A method of enriching a human infant formula, comprising admixing a bioactive ingredient into the human infant formula, said bioactive ingredient being encapsulated according to the method of claim 88, thereby enriching the human infant formula.

109. (Withdrawn) The method of claim 108, wherein the human infant formula is a milk replacer, a milk substitute or a combination thereof.

110. (Withdrawn) The method of claim 88, wherein said at least one additional encapsulating layer material comprises food grade material, feed grade material either alone or in combination.

111. (Withdrawn) The formulation of claim 101, wherein the formulation is a feed in form of pellets, mash, liquid, or a combination thereof.

112. (Withdrawn) The method of claim 88, wherein the step of coating further comprises a step of grinding the coated dry blend.

113. (Withdrawn) The method of claim 88, wherein the formulation is a food or feed and the step of adding the dry blend to the mammalian food or feed formulation further includes

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premixing the blend in a small volume of the mammalian newborn food or feed for ensuring homogeneity.

114. (Withdrawn) The formulation of claim 101, wherein formulation is a feed and the step of mixing comprises adding the bioactive material as an emulsion.

115. (Withdrawn) The formulation of claim 114, wherein the emulsion is a nano-emulsion, a microemulsion or a combination thereof.

116. (New) The method of claim 106, wherein the newborn food or feed is a human infant formula.

117. (New) The method of claim 106, wherein the newborn food or feed is a milk replacer, a milk substitute or a combination thereof.

118. (New) The method of claim 106, wherein the heat sensitive bioactive ingredient is selected from the group consisting of insulin, a glycoprotein, an immunoglobulin, a peptide, a polypeptide, a hormone, an enzyme, IGF-I, IGF-II, EGF alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component or complexes of soluble CD4, tissue plasminogen activator, a pharmaceutically acceptable salt thereof, an analog thereof, a variant thereof or a combination thereof.

119. (New) The method of claim 118, wherein the heat sensitive bioactive ingredient is insulin.

120. (New) The method of claim 106, wherein the mammalian newborn food or feed is specifically formulated for the consumption of the genera of primate, bovine, ovine, canine, feline, and caprine.